

Food and Drug Administration, HHS

§ 558.3

558.78 Bacitracin zinc.
 558.95 Bambermycins.
 558.105 [Reserved]
 558.115 Carbadox.
 558.120 Carbarsone (not U.S.P.).
 558.128 Chlortetracycline.
 558.140 Chlortetracycline and
 sulfamethazine.
 558.145 Chlortetracycline, procaine peni-
 cillin, and sulfamethazine.
 558.155 Chlortetracycline, sulfathiazole,
 penicillin.
 558.175 Clopidol.
 558.185 Coumaphos.
 558.195 Decoquinolate.
 558.198 Diclazuril.
 558.205 Dichlorvos.
 558.235 Efrotomycin.
 558.248 Erythromycin thiocyanate.
 558.254 Famphur.
 558.258 Fenbendazole.
 558.261 Florfenicol.
 558.265 Halofuginone hydrobromide.
 558.274 Hygromycin B.
 558.295 Iodinated casein.
 558.300 Ivermectin.
 558.305 Laidlomycin.
 558.311 Lasalocid.
 558.325 Lincomycin.
 558.340 Maduramicin ammonium.
 558.342 Melengestrol.
 558.348 Mibolerone.
 558.355 Monensin.
 558.360 Morantel tartrate.
 558.363 Narasin.
 558.364 Neomycin sulfate.
 558.365 Nequinolate.
 558.366 Nicarbazine.
 558.369 Nitarsone.
 558.415 Novobiocin.
 558.430 Nystatin.
 558.435 Oleandomycin.
 558.450 Oxytetracycline.
 558.455 Oxytetracycline and neomycin.
 558.460 Penicillin.
 558.464 Poloxalene.
 558.465 Poloxalene free-choice liquid Type C
 feed.
 558.485 Pyrantel.
 558.500 Ractopamine.
 558.515 Robenidine hydrochloride.
 558.530 Roxarsone.
 558.550 Salinomycin.
 558.555 Semduramicin.
 558.575 Sulfadimethoxine, ormetoprim.
 558.582 Sulfamerazine.
 558.586 Sulfaquinoxaline.
 558.600 Tiamulin.
 558.615 Thiabendazole.
 558.618 Tilmicosin.
 558.625 Tylosin.
 558.630 Tylosin and sulfamethazine.
 558.635 Virginiamycin.
 558.665 Zilpaterol.
 558.680 Zoalene.

AUTHORITY: 21 U.S.C. 360b, 371.

SOURCE: 40 FR 13959, Mar. 27, 1975, unless
 otherwise noted.

Subpart A—General Provisions

§ 558.3 Definitions and general consid- erations applicable to this part.

(a) Regulations in this part provide for approved uses of drugs and combinations of drugs in animal feeds. Approved combinations of such drugs are specifically identified or incorporated by cross-reference. Unless specifically provided for by the regulations, a combination of two or more drugs is not approved.

(b) The following definitions apply to terms used in this part:

(1) New animal drugs approved for use in animal feed are placed in two categories as follows:

(i) Category I—These drugs require no withdrawal period at the lowest use level in each species for which they are approved.

(ii) Category II—These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required, or are a veterinary feed directive drug.

(2) A “Type A medicated article” is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(3) A “Type B medicated feed” is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated

feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term “highest continuous use level” means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(4) A “Type C medicated feed” is intended as the complete feed for the animal or may be fed “top dressed” (added on top of usual ration) on or offered “free-choice” (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under § 515.20 of this chapter.

(5) A Type B or Type C medicated feed manufactured from a drug component (bulk or “drum-run” (dried crude fermentation product)) requires an application approved under § 514.105 of this chapter or an index listing granted under § 516.151 of this chapter.

(6) A “veterinary feed directive (VFD) drug” is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) or listed in the index under section 572 of the act for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A “veterinary feed directive” is a written statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug in or on

an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client’s animals only in accordance with the directions for use approved or indexed by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A “medicated feed” means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a “distributor” means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An “animal production facility” is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An “acknowledgment letter” is a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar written acknowledgment letter.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007]

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified: